REMARKS

The claims have been amended to clarify the invention. In particular, claim 21 has been amended to delete a variant of the amino acid sequence of SEQ ID NO:15. No new matter is added by this amendment, and entry of the amendment is requested.

35 U.S.C. 112, First Paragraph, Rejection of Claim 21

The Examiner has rejected claim 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which is not described in the specification in such a was as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner stated that new claim 21 embraces all polynucleotides that encode SEQ ID NOs:14 and 15 and all polynucleotides that encode variants of SEQ ID NOs:14 and 15 that are 95% or more identical to SEQ ID NOs:14 and 15. Applicants have not pointed to [any] basis in the application as filed for the full breadth of the claim.

Applicants Response

Applicants disagree that they have not pointed out any basis for new claim 21 in the specification as filed. Support for a polynucleotide " encoding a polypeptide having and amino acid sequence of SEQ ID NO:14 or SEQ ID NO:15" was cited as specifically found at page 23, lines 29-30; ("SEQ ID NOs:14 and 15 of the present invention were encoded by SEQ ID NOs:1 and 8, respectively"), and for "a naturally occurring variant having at least 95% sequence identity to the amino acid sequence of SEQ ID NO:14 or SEQ ID NO:15" at page 3, line 20; (naturally occurring protein), and at page 3, lines 29-30; ("A variant" refers to a polynucleotide or protein whose sequence diverges from about 5% to about 30% from the nucleic acid or amino acid sequences of the Sequence Listing"), which clearly encompasses a variant "having at least 95% identity" to SEQ ID NO:14 or SEQ ID NO:15. Withdrawal of the rejection is therefore requested.

35 U.S.C. 101, Rejection of Claim 15

The Examiner has maintained the rejection of claim 15 under 35 U.S.C. 101, because the claimed invention lacks patentable utility essentially for the reasons already of record (e.g., Office Action mailed January 21, 2003). The Examiner stated that applicants argument in connection with mRNA expression levels is not relevant because applicants do not assert a

patentable utility for the polypeptides themselves (underline added). The Examiner stated that since the claim is drawn to a method for producing polypeptides, the instant application must disclose a patentable utility for the polypeptides or a patentable utility for the polypeptides mentioned in the claims must be readily apparent to one of skill in the art. Neither requirement is met here. The Examiner stated, however, that applicants argument in connection with SEQ ID NOs:1 and 8 encoding SEQ ID NOs:14 and 15, respectively, is persuasive.

Applicants Response

Applicants disagree that the application does not assert a patentable utility for the disclosed polypeptides, SEQ ID NOs:14 and 15, or that a patentable utility for the polypeptides mentioned in the claims is not readily apparent to one of skill in the art. Applicants further disagree that applicants argument in connection with mRNA expression levels is not relevant to the rejection.

The Examiners' previous rejection, referenced by the Examiner above, specifically stated at page 3, bottom of the page "The instant application does not disclose that any one of the polypeptides that may be encoded by SEQ ID NOs:1, 4 and 8 is actually expressed *in vivo* .... Thus, there is no disclosed utility for such polypeptides ...". Applicants argument regarding mRNA expression levels and their generally accepted equivalence with expressed protein levels was directed specifically to this grounds of the rejection. Therefore, having acknowledged that the polynucleotides of SEQ ID NOs:1 and 8 are adequately disclosed in the specification as encoding the polypeptides of SEQ ID NOs:14 and 15, respectively, the Examiner must conclude that, absent specific evidence to the contrary, the claimed polynucleotides and their encoded proteins are most likely similarly expressed for the reasons previously given, and are therefore both useful as surrogate markers for the detection and diagnosis of the disclosed pancreatic disorders. In addition to such a utility being readily apparent to the skilled artisan, such a utility is specifically disclosed in the specification, e.g., at page 2, lines 18-19 (The invention provides a method of using a protein to make an antibody that specifically binds the protein of the invention, and methods of using the antibody to diagnose or treat a pancreatic disorder); and at page 12, lines 24-25 (In another embodiment, antibodies or Fabs comprising an antigen binding site that specifically binds the protein can be used for the diagnosis of diseases characterized by the differential expression of the protein). Thus, a utility for the polypeptides or the polynucleotides

of the invention in the detection and diagnosis of pancreatic disorders is both specifically asserted by applicants as well as readily apparent to the skilled artisan. Withdrawal of the rejection of claim 15 under 35 U.S.C. 101 is therefore requested.

35 U.S.C. 102(a), Rejection of Claim 21

The Examiner has rejected claim 21 under 35 U.S.C. 102(a) as being anticipated by Koyama et al. (Genomics 54:169, 1988). Koyama et al discloses a cDNA that encodes a polypeptide that differs by only one amino acid from SEQ ID NO:15. This results in a 99.8% sequence identity between the sequence of Koyama and SEQ ID NO:15. The sequence of Koyama is longer by six amino acids compared to SEQ ID NO:15, so at the very least, the Examiner stated, the Koyama sequence matches SEQ ID NO:15 at 97.25% identity and thus the polypeptide sequence of Koyama et al. qualifies as a variant of SEQ ID NO:15 as defined in the claim and the cDNA of Koyama et al is embraced by the claim.

Applicants Response

Claim 21 has been amended to delete variants of SEQ ID NO:15 and therefore Koyama et al. no longer anticipate the claimed polynucleotides. Withdrawal of the rejection of claim 21 as anticipated by Koyama et al. is therefore requested.

Allowed Claims

The Examiner stated that claims 1-3, 13 and 14 are allowable over the prior art of record.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited. Applicants further request that the Examiner, having allowed claims 1 and 2, now rejoin and examine claims 4-12 as methods of use of the polynucleotides of claims 1 and 2 that depend from and are of the same scope as claims 1 and 2 in accordance with *in Re Ochiai* and the MPEP § 821.04.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

INCYTE CORPORATION

Date: August 20, 2003

David G. Streeter, Ph.D.
Reg. No. 43,168
Direct Dial Telephone: (650) 845-5741

Customer No.: 27904
3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886